

3M ESPE

RelyX™ Luting Cement
RelyX™ Luting Plus Cement

technical product profile

RelyX™

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Introduction

RelyX™ Luting Cement and RelyX™ Luting Plus Cement from 3M ESPE are self-curing, radiopaque, fluoride-releasing, resin-modified glass ionomer luting cements. They are indicated for the permanent cementation of metal-based and strengthened-core ceramic restorations, posts and orthodontic appliances.

The primary purpose of a luting cement is to aid in retaining and sealing fixed prosthetic devices to prepared teeth. The better the crown preparation on the tooth (long axial walls with an approximate 6° taper) and the better the crown fit at the margins, the less a clinician has to rely on the retentive properties of the cement. Glass ionomer-based cements provide excellent properties for the retention of these types of restorations.

The RelyX Luting cement and RelyX Luting Plus cement will provide for molecular bonding to the tooth surface without the use of a separate tooth conditioner, good strength properties, fluoride ion release, and low solubility or acid erosion of the margins in an easy to use, non-technique sensitive procedure.

History

Clinicians have many options for luting routine crown and bridge restorations. They range from zinc phosphates, polycarboxylates, conventional glass ionomers, resin-modified glass ionomers, compomers and resin cements. In the North American markets, the conventional and resin-modified glass ionomer luting cements have become the most frequently used for routine crown and bridge restorations. Resin cements have been used for special situations where added retention is required, however they traditionally required multiple steps and have been technique sensitive. However, with the introduction of the unique RelyX™ Unicem Self-Adhesive Universal Resin Cement from 3M ESPE, clinicians now have an easy to use resin cement that offers low potential for sensitivity and is gaining in popularity for these types of restorations.

A comparison of the various classes of luting cements is provided in Table 1.

Table 1. Luting Cement Comparison

| Strengths | Areas of Application | Weaknesses |
|--|--|---|
| Zinc Phosphate Cement Over 100 years of clinical experience | Routine application in metal supported crowns and bridges | Occasional postoperative sensitivity Low hardness High solubility |
| Polycarboxylate Cement 25 years of clinical experience | Acceptable for retention of metal supported crowns and bridges | High solubility |
| Low fluoride ion release Molecular bonding to the tooth surface Low postoperative sensitivity | Long-term provisional restorations | Low hardness |
| Conventional Glass Ionomer Cement 20 years of clinical experience | Routine application for metal supported crowns and bridges | Occasional postoperative sensitivity |
| Fluoride ion release Molecular bonding to the tooth surface Minimal dimensional change Simplicity of use Medium material strength Good routine cement | Limited application with high strength ceramics | Sensitive to water and mechanical loading Solubility |
| Resin-Modified Glass Ionomer Cement 10 years of clinical experience | Routine application for metal supported crowns and bridges | Moisture sensitive powder |
| Fluoride ion release Molecular bonding to the tooth surface Low solubility or erosion of cement margins Simplicity of use Medium material strength Good routine cement Low postoperative sensitivity | Limited application with high strength ceramics | Swelling/linear expansion |

| Strengths | Areas of Application | Weaknesses |
|--|--|---|
| Compomer Cements | | |
| Easy technique | Metal-supported restorations | Little long-term experience |
| Good adhesive qualities (with pretreatment: etching, priming, bonding) | Most all-ceramic systems | Moisture sensitive |
| | Indirect composite restorations | Low or no fluoride release |
| Low solubility | Lining material | |
| Good mechanical properties | Emergency provisional restoration | |
| Resin Cements (Composite) | | |
| 10-20 years of clinical experience | All metal-based, ceramic and indirect composite restorations | Difficult to use |
| High adhesion with use of pretreatments (etching, priming, bonding) | | Requires use of separate primers or adhesives |
| High hardness | | Difficult clean up |
| Low solubility | | Technique sensitive |
| High mechanical properties | | No or little fluoride release |
| Good esthetics | | Potential for postoperative sensitivity |
| Self-Adhesive Resin Cements (RelyX™ Unicem Self-Adhesive Resin Cement from 3M ESPE) | | |
| New self-adhesive technology | All metal-based, ceramic and indirect composite restorations with the exception of veneers | Limited long-term clinical history |
| High adhesion without use of etchant, primer or adhesive | | Available only in capsule delivery |
| Ease of use | | Low fluoride release |
| Capsule delivery system | | |
| Low potential for postoperative sensitivity | | |
| High hardness | | |
| Low solubility | | |
| High mechanical properties | | |
| Good esthetics | | |
| Easy clean up | | |

Product Description

RelyX™ Luting Cement (formerly known as Vitremer™ Luting Cement when first launched) was first introduced into the market in 1994. The product consists of a powder and liquid, which are dispensed in a 1:1 scoop:drop ratio, and mixed by hand for 30 seconds. The working time of the mixed cement is 2.5 minutes. The resulting mix has a mousse-like consistency, which is easily loaded into the restoration and allows for easy seating of the restoration. The excess cement is then easily cleaned-up after 2-3 minutes in the mouth. The RelyX Luting cement quickly gained in popularity of use for its ease of use, handling and clean-up properties, and low incidence of post-operative sensitivity. It has been a market leader for many years.

As with any hand-mixed, powder/liquid system, there can occasionally be an issue with the ease of use and consistency in dispensing the proper powder/liquid ratios, which if not done properly, can result in variance of the setting properties of the cement. Additionally, some of the powders can be sensitive to moisture uptake or contamination, which can also result in a variance of the setting properties of the cement. Therefore, there has been a strong desire to develop an easier to use paste/paste system that would overcome these variables and provide a product that could deliver greater consistency of use.

RelyX™ Luting Plus Cement is a paste/paste, resin-modified glass ionomer luting cement dispensed in a larger Clicker™ Dispenser system from 3M ESPE. The Clicker dispenser is similar to the Clicker dispenser used with the RelyX™ ARC Resin Cement system also from 3M ESPE, but is 2.3 times larger. The RelyX Luting Plus cement pastes are easily dispensed out of the Clicker dispenser and hand-mixed for 20 seconds. The working time of the mixed cement is 2.5 minutes. As with the powder/liquid system, the mixed cement from the paste/paste has the same mousse-like consistency, which is easily loaded into the restoration, and allows for easy seating of the restoration. The excess cement can also be easily cleaned up after 2 minutes in the mouth with final set being achieved in 5 minutes. The paste/paste system will provide for an even easier to use system and provide for more consistent use when compared to the powder/liquid system.

For both RelyX Luting cement and RelyX Luting Plus cement, the setting reactions are very similar. Two setting reactions occur for each system, an acid-base reaction between the fluoroaluminosilicate glass and the methacrylate functionalized polycarboxylic acid (this is the true glass ionomer setting reaction) and a free radical polymerization of the pendant methacrylate groups of the polymer and HEMA (2-hydroxyethylmethacrylate). The free radical polymerization reaction takes place without the need for light activation, therefore it is self-curing. The additional methacrylate reactions provides for higher strengths and reduced marginal solubility without sacrificing adhesion or fluoride release. Because of this chemistry, the cements can be described as resin-modified glass ionomer cements.

Indications for Use

RelyX Luting cement and RelyX Luting Plus cement are indicated for luting the following types of restorations:

- Porcelain-fused-to-metal (PFM) crowns and bridges
- Metal crowns, bridges, inlays and onlays
- Prefabricated metal provisional crowns
- Strengthened core all-zirconia or all-alumina ceramic crowns and bridges (i.e. Lava™ All-Ceramic System from 3M ESPE or Procera® AllCeram)
- Prefabricated or cast posts
- Orthodontic appliances

Composition

RelyX™ Luting Cement

RelyX Luting cement is composed of a powder and a liquid. The powder and liquid are mixed in a 1.6: 1 ratio by weight, which equates to 1 scoop of powder to 1 drop of liquid.

The RelyX Luting cement powder is composed of a radiopaque fluoroaluminosilicate glass (FAS glass). It contains a microencapsulated potassium persulfate and ascorbic acid catalyst system providing the methacrylate cure in the absence of light (self-cure). The powder also contains an opacifying agent for shading to allow differentiation from the tooth.

The RelyX Luting cement liquid is an aqueous solution of polycarboxylic acid modified with pendant methacrylate groups. It also contains HEMA, water and small amounts of tartaric acid.

| Powder | Liquid |
|-----------------------------------|-----------------------------------|
| Fluoroaluminosilicate (FAS) glass | Methacrylated polycarboxylic acid |
| Potassium persulfate | Water |
| Ascorbic acid | HEMA |
| Opacifying agent | Tartaric Acid |

RelyX™ Luting Plus Cement

RelyX Luting Plus cement is composed of two separate pastes dispensed out of the Clicker™ Dispenser in a 1:1 volume ratio.

The RelyX Luting Plus cement Paste A is composed of a radiopaque fluoroaluminosilicate glass (FAS glass), opacifying agent, HEMA, water, a proprietary reducing agent that allows for the self-cure methacrylate setting, and a dispersion aid.

The RelyX Luting Plus cement Paste B is composed of a non-reactive zirconia silica filler, the methacrylated polycarboxylic acid, HEMA, BisGMA, water and potassium persulfate.

| Paste A | Paste B |
|-----------------------------------|-----------------------------------|
| Fluoroaluminosilicate (FAS) glass | Methacrylated polycarboxylic acid |
| Proprietary reducing agent | BisGMA |
| HEMA | HEMA |
| Water | Water |
| Opacifying agent | Potassium persulfate |
| | Zirconia silica filler |

Properties

In order to achieve proper performance, the cements must provide for a variety of physical properties with respect to adhesion, strength, film thickness, work time, set time and radiopacity.

The glass ionomer based cements are regulated under the ISO 9917:2003 standard for Dental Water Based Cements and Self-curing Resin Modified Cements. The RelyX™ Luting Cement and RelyX™ Luting Plus Cement both pass the requirements for the ISO 9917 standard.

The physical properties of the RelyX Luting cement and RelyX Luting Plus cement are described and shown in this section. Additionally, results for the following cements are also provided for most tests:

| | |
|-----------------|--|
| GC's FujiCEM™ | (paste/paste resin modified glass ionomer) |
| GC's Fuji Plus™ | (powder/liquid resin modified glass ionomer) |
| GC's Fuji 1® | (powder/liquid conventional glass ionomer) |

Adhesion to Tooth Structure

An advantage of the glass ionomer cements is their inherent ability to provide a molecular bond to tooth structure without the use of separate etching and bonding techniques. Although, some products do recommend the use of a separate conditioner on the tooth surface to promote adhesion, RelyX Luting cement and RelyX Luting Plus cement do not need a separate conditioning step. While the adhesion is lower than that of properly placed composite resin systems, clinical experience has proven it to be adequate for most metal-based or strengthened-ceramic restorations.

Bovine dentin and enamel substrates were prepared by potting the teeth in acrylic, then grinding and polishing to expose the enamel or dentin surface. Sandblasted metal test buttons were used to simulate the restoration. Cements were mixed according to manufacturer's directions and placed onto the metal surface. The metal buttons were then seated onto the tooth surface under moderate pressure. The samples were placed into a heated humidity chamber (37°C/95%RH) for 20 minutes, and then placed into distilled water. The samples were stored at 37°C for 24 hours and the shear adhesion results were measured using an Instron test machine. Figures 1 and 2 show the adhesion results for both enamel and dentin. RelyX Luting cement and RelyX Luting Plus cement show similar results for adhesion.

Source: 3M ESPE Laboratory test data

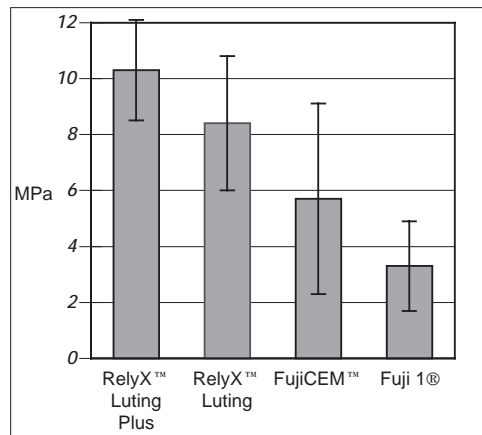


Figure 1. Shear Adhesion to Enamel

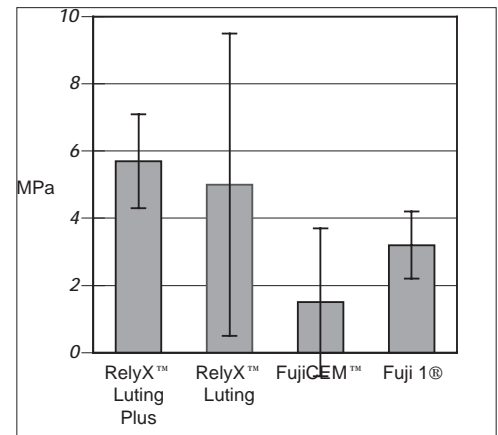
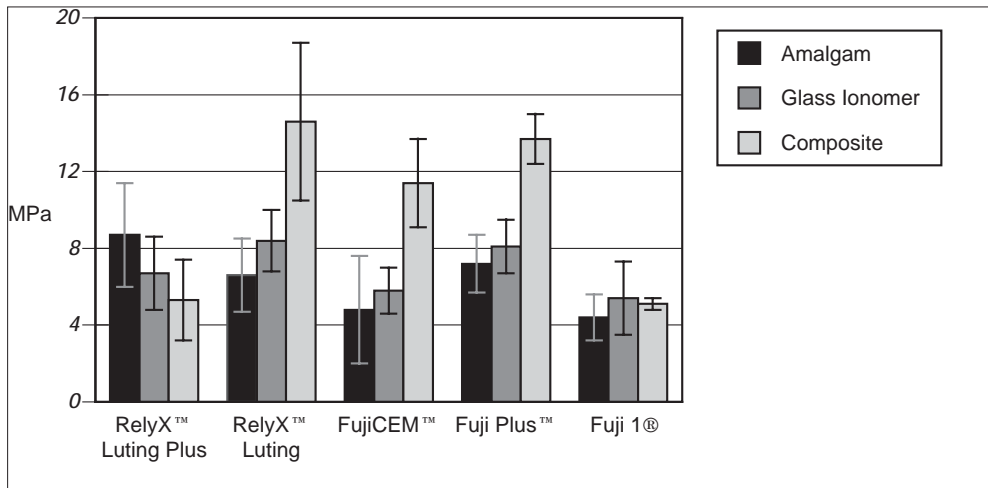


Figure 2. Shear Adhesion to Dentin

Adhesion to Core Build-Up Substrates

In addition to bonding to tooth structure, the cements must also be able to bond to various types of core build-up materials that may be used as a base under indirect restorations. The common types of build-up materials include amalgam, glass ionomer, and composite resins. In this test, the cements were tested for adhesion in a similar manner to that described above for the dentin and enamel.

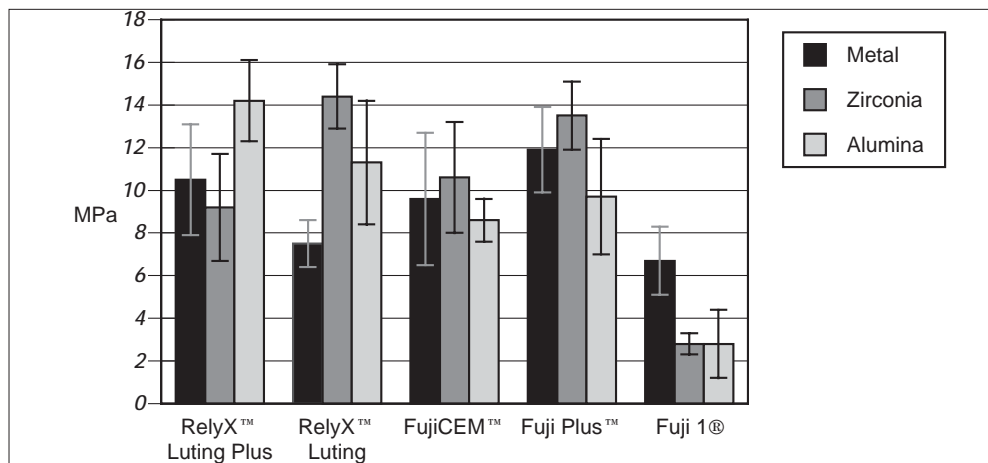


Source: 3M ESPE Laboratory test data

Figure 3. Adhesion to Core Build-up Substrates

Adhesion to Restorative Substrates

In addition to bonding to the tooth structure and the core build-up substrates, the cements must also be able to bond to the various restorative substrates, for which they are indicated. The primary restorative substrates that are indicated for the resin-modified glass ionomers are metal, alumina and zirconia. In this test, the cements were tested sandblasted metal (Rexillum III), Lava™ All-Ceramic zirconia and Procera® AllCeram alumina buttons were bonded to enamel in a similar procedure as described above.



Source: 3M ESPE Laboratory test data

Figure 4. Adhesion to Restorative Substrates

Mechanical Properties

A metal-based and strengthened-core ceramic restoration gains much of its supporting strength and stability from the coping and does not rely as heavily on the cement as is the case with weaker strength ceramics where composite resin cements are indicated and needed for support. The compressive and flexural strength of the cements were measured in accordance with the ISO 9917 test standard. Additionally, the diametral tensile strength of the cements was also measured. The cements tested provided for similar results for the three strength measurements with the exception of the Fuji 1® 1 conventional glass ionomer, which was significantly lower for flexural strength.

Source: 3M ESPE Laboratory test data

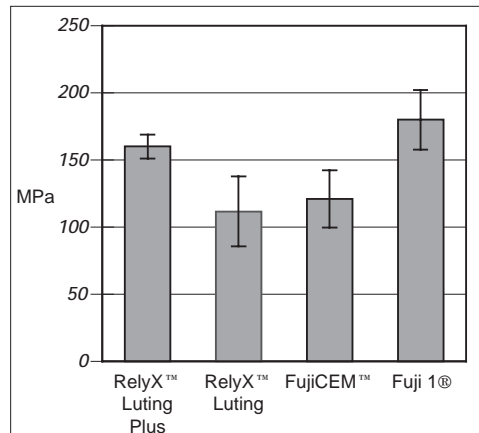


Figure 5. Compressive Strength

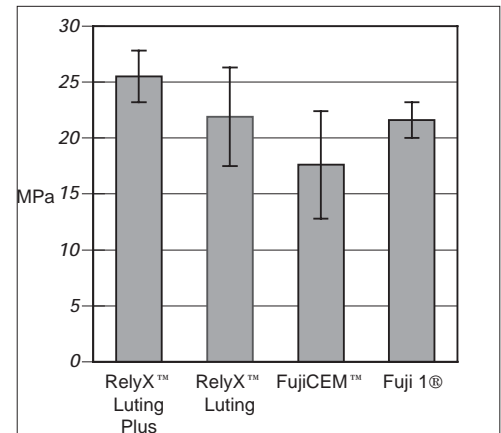


Figure 6. Diametral Tensile Strength

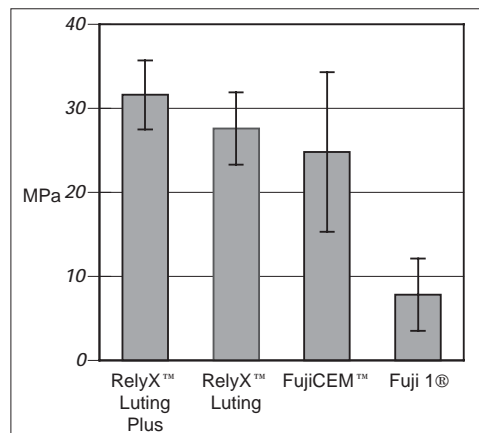


Figure 7. Flexural Strength

Film Thickness

The film thickness of the cement plays an important role in determining how well a precision indirect restoration will fit. Film thickness is determined by placing the mixed cement between two glass plates and placing a load on the top plate to see how thin the cement layer can get. A material with a low film thickness has the ability to allow a very tight fitting indirect restoration to seat completely. This test was conducted in accordance with ISO 9917 and requires the film thickness to be less than 25 microns. The results show that all of the cements were below the 25 micron limit.

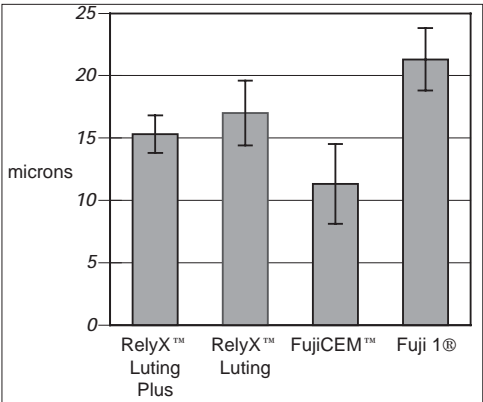


Figure 8. Film Thickness

Source: 3M ESPE Laboratory test data

Radiopacity

Radiopacity is important during an indirect procedure for two reasons, it allows the doctor to discover any excess material subgingivally and allows the doctor to discover any large marginal discrepancies. Radiopacity allows the clinician to distinguish the cement from tooth structure on an x-ray. The radiopacity was measured in accordance with the ISO 9917 test standard. The test compares the radiographical density of the cement test sample to that of aluminum. A value of 1.0 or greater is considered to be radiopaque. The results show that all of the cements were in a similar range are considered to be radiopaque.

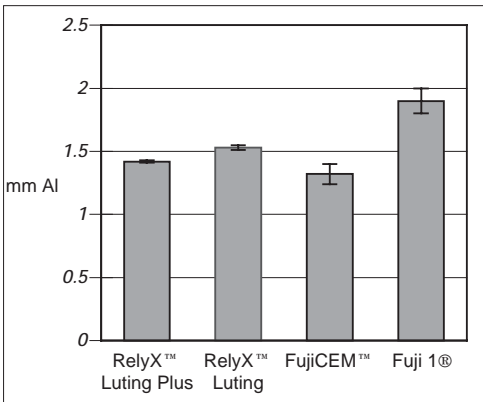


Figure 9. Radiopacity

Source: 3M ESPE Laboratory test data

Fluoride Release

One of the key features of a glass ionomer-based cement is their sustained fluoride release. It is generally believed that the release of fluoride ions and uptake into the tooth structure aids in the reduction of secondary caries¹, which can be difficult to detect under a crown or bridge. Fluoride release was measured in-vitro in a buffer solution using a fluoride ion-specific electrode. The chart shows the sustained release of both RelyX™ Luting Cement and RelyX™ Luting Plus Cement in comparison to the other resin-modified glass ionomers and the conventional glass ionomer (Ketac™ Cem Glass Ionomer Luting Cement from 3M ESPE).

Source: 3M ESPE Laboratory test data

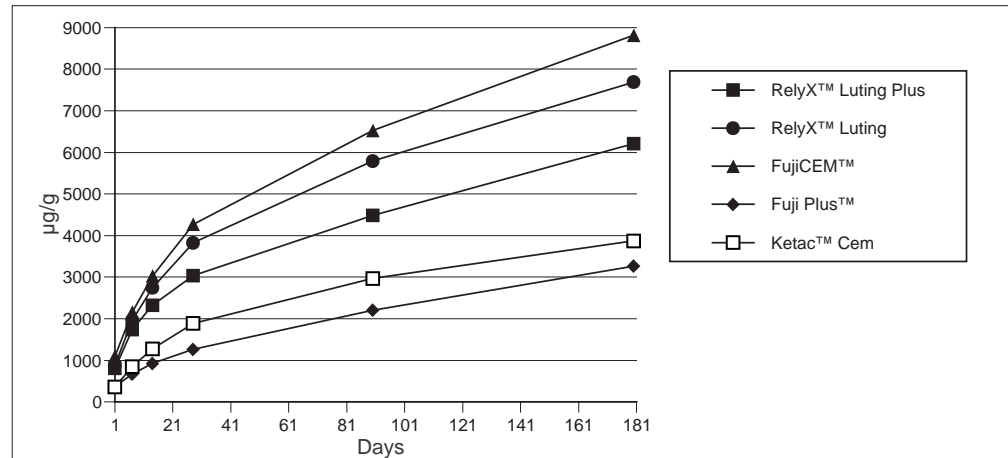


Figure 10. Cumulative Fluoride Release

Field Evaluation Results

With the introduction of the RelyX Luting Plus cement, a clinical use field evaluation was conducted. 137 dentists cemented a total of 1889 restorations with the RelyX Luting Plus cement. The observation period was approximately 6 weeks. The dentists completed a questionnaire regarding their experiences in use and application of the product.

The dentists that participated in the study used a variety of cement types for their routine cementation including resin cements, resin-modified glass ionomers, conventional glass ionomers, polycarboxylates, and zinc phosphate.

Figure 11 shows the range and numbers of types of restorations that were placed during the evaluation.

Source: 3M ESPE Laboratory test data

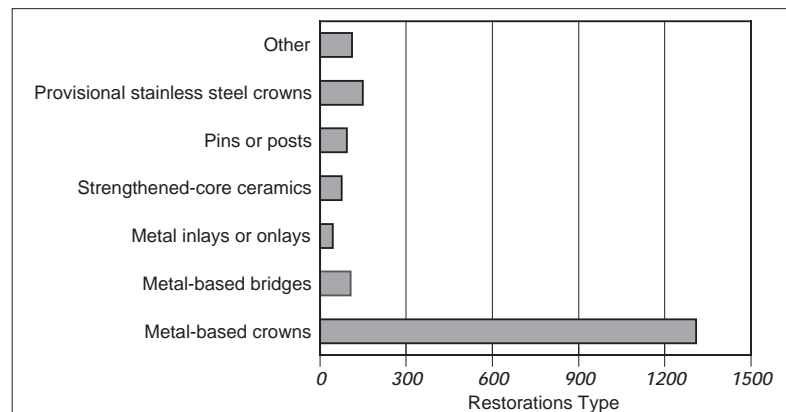


Figure 11. Types of Restorations

¹ Hicks MJ, Flaitz CM, Quintessence Int. 2000 Sep;31(8): 570-8.

Clinicians were asked to rate various handling properties of the RelyX™ Luting Plus Cement on a scale of 1 to 5 with a 1 being completely dissatisfied and a 5 being completely satisfied.

Figure 12 shows the average rating for the various properties and the percentage of clinicians that stated they were satisfied to completely satisfied. Overall, clinicians were very satisfied with all attributes and performance of the RelyX Luting Plus cement.

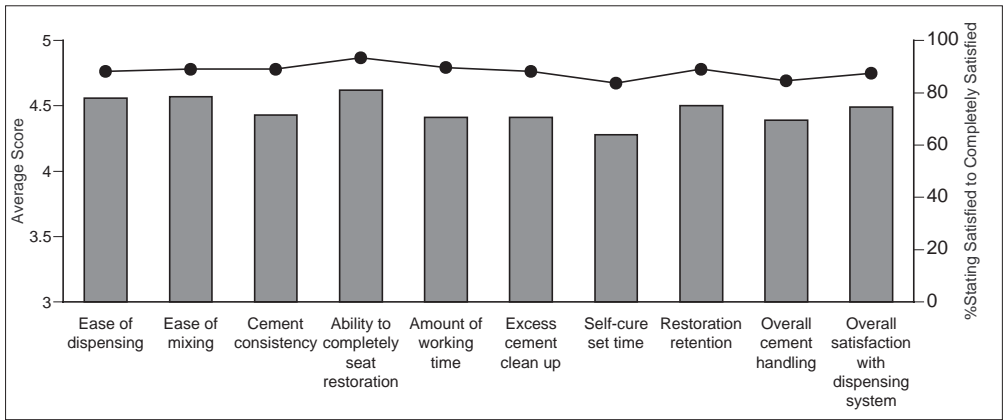


Figure 12. Overall satisfaction with RelyX Luting Plus cement

Clinicians were asked to rate various properties of the new larger Clicker™ Dispenser on a scale of 1 to 5 with a 1 being completely dissatisfied and a 5 being completely satisfied.

Figure 13 shows the average rating for the various properties and the percentage of clinicians that stated they were satisfied to completely satisfied. Overall, the clinicians were very satisfied with the new larger Clicker dispenser.

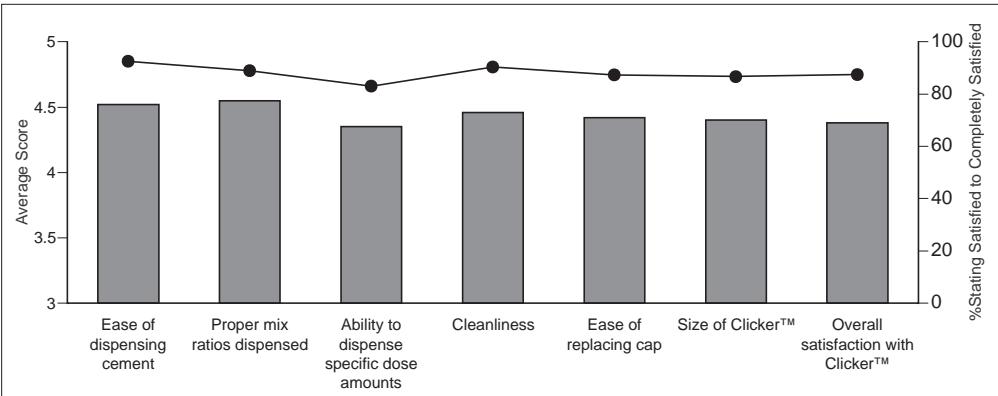


Figure 13. Satisfaction with the Clicker dispenser

Clinicians were also asked to rate how well the RelyX™ Luting Plus Cement met their overall expectations for a routine crown and bridge luting cement. They were asked to rate their satisfaction on a scale of 1 to 5 with 1 corresponding to not meeting expectations at all and a 5 corresponding to completely met expectations. Figure 14 shows the average rating for meeting expectations and the percentage of clinicians that stated that the product either generally met or completely met expectations. The results were determined for the various user groups. Overall, the cement met the clinician's expectations very well.

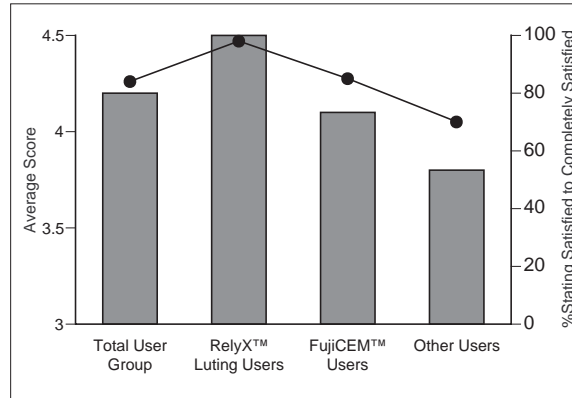


Figure 14. Overall Satisfaction with RelyX Luting Plus cement

The clinicians that currently use the powder/liquid RelyX Luting cement were asked if they felt that the paste/paste RelyX Luting Plus cement would provide more consistent performance, by eliminating the variability with dispensing separate powders and liquids.

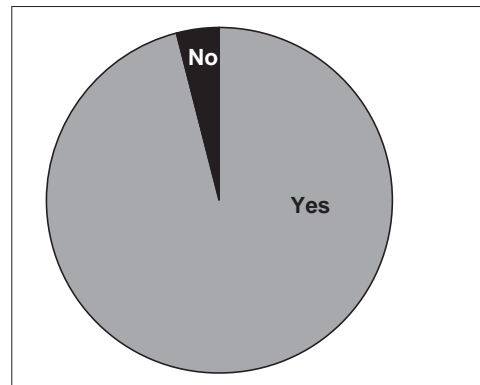


Figure 15. Consistency of RelyX Luting Plus cement

Technique Guides

3M ESPE CROWN AND BRIDGE CEMENTATION

RelyX™ Luting Cement

Indications:

- For permanent cementing of:
 - Porcelain-fused-to-metal crowns and bridges
 - Metal inlays, onlays, crowns and bridges
 - Crowns made with all-alumina or all-zirconia cores such as Procera® AllCeram and Lava™ All-Ceramic System
 - Pre-fabricated and cast endodontic posts
- Cementing orthodontic bands

Tooth Preparation:

- Remove provisional restoration and all temporary cement.
- Clean tooth with oil-free pumice paste, rinse, and dry.
- DO NOT DESSICATE THE TOOTH.

Mixing:

- Use an equal number of powder scoops and liquid drops.
- Fluff the powder. Dispense 3 level scoops for crown, 6 for bridge.
- Hold liquid vial vertically and dispense 3 drops for crown, 6 for bridge. Keep the vial tip clean.
- Mix all the powder into the liquid, about 30 seconds.



Load the crown/bridge:

- Spread the cement over all the internal surfaces of the crown/bridge.
- Working time is 2.5 minutes.



Placement:

- Seat the crown/bridge.
- Wait at least 3 minutes after placement.
- Remove excess cement with an appropriate instrument.



3M ESPE Customer Hotline 1-800-634-2249
Please refer to instructions for more detailed information
as well as precautionary and warranty information.

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44-0019-9255-9B
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RelyX™ Luting Plus Cement
Indications:

For permanent cementation of:

- Porcelain-fused-to-metal crowns and bridges
- Metal crowns, bridges, inlays and onlays (including prefabricated provisional metal crowns).
- All-zirconia or all-alumina strengthened core restorations
- Prefabricated or cast endodontic posts

Cementing orthodontic bands

Tooth Preparation:

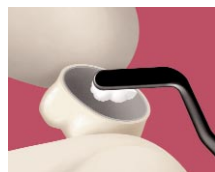
- Remove provisional restoration and all temporary cement.
- Clean tooth with oil-free pumice paste, rinse and lightly dry leaving tooth surface moist.
- DO NOT OVERDRY THE TOOTH

Dispensing and Mixing:

- Remove cap and dispense desired amount of cement onto mixing pad. 1-2 “Clicks” of material are sufficient for a single tooth restoration.
- **Note: To avoid water evaporation and drying out of the cement pastes, dispense and mix cement immediately prior to use.**
- Replace cap securely onto Clicker™ dispenser until an audible click is heard.
- Mix cement with spatula for 20 seconds.


Load Cement Into Restoration:

- Working time of mixed cement is 2.5 minutes.
- Apply thin layer of cement to the inside surface of the restoration.


Placement of Restoration:

- Seat restoration with light pressure.
- Excess cement can be removed after 2 minutes in the mouth with an appropriate instrument (e.g. explorer, scaler).
- Set time is 5 minutes after placement in the mouth.
- Finish restoration and adjust occlusion.



3M ESPE Technical Hotline 1-800-634-2249
Please refer to Instructions for Use for more detailed information as well as precautionary and warranty information.

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Instructions for Use

RelyX™ Luting Cement

Description of Product

RelyX Luting cement, manufactured by 3M ESPE, is a glass ionomer system comprised of two parts: a powder and a liquid. The powder is a radiopaque, fluoroaluminosilicate glass. The liquid is an aqueous solution of a modified polyalkenoic acid. RelyX Luting cement provides the major benefits of glass ionomer cements – adhesion to tooth structure, fluoride release along with additional benefits of low solubility, improved fracture toughness and a low viscosity, non-stringy, slump-resistant mix.

Indications For Use

RelyX Luting cement is indicated for use when luting:

- Porcelain fused to metal crowns and bridges to tooth structure, amalgam, composite or glass ionomer core build-ups
- Metal inlays, onlays or crowns
- Crowns made with all-alumina or all-zirconia cores such as Lava™ All-Ceramic System or Procera® AllCeram.
- Prefabricated and cast post cementation
- Orthodontic appliances

RelyX Luting cement is not indicated for composite or porcelain inlays or onlays, or composite or all-ceramic crowns not having all-alumina or all-zirconia cores.

Precautions for Dental Personnel and Patients

RelyX Luting cement liquid contains HEMA (2-hydroxyethylmethacrylate). Avoid use of this product on patients with known acrylate allergies. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured resins. Use of protective gloves and a no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly used gloves. If cement contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If accidental contact with eyes or prolonged contact with oral soft tissue occurs, flush with large amounts of water. If irritation persists, consult a physician.

Liquid and powder/liquid mix may cause eye irritation upon contact and may be mildly irritating to oral soft tissue upon contact. Avoid contact with eyes and minimize contact with oral soft tissue. If accidental contact with eye occurs, flush immediately with large amounts of water. If irritation persists, consult a physician.

Instructions for Use

1. Remove the provisional restoration and all residual temporary cement. Thoroughly clean the preparation with an oil-free pumice paste. Rinse with water and let dry.

Note: Do not desiccate the tooth. Desiccation of tooth structure is believed to cause postoperative sensitivity in some individuals.

2. Pulp Protection: Use a hard setting calcium hydroxide material with near exposures.

NOTE: Use of some tooth preparation treatments is contraindicated as their residue may adversely affect bond strength or the setting reactions (e.g., Tubulicid Red).

Contact your local 3M ESPE representative or the 3M ESPE Customer Hotline for specific details.

3. Casting preparation: Thoroughly clean interior surfaces of cast crown, inlay or onlay
4. Dispense powder and liquid: The standard powder/liquid ratio of 1.6:1 by weight can be obtained by using an equal number of level scoops of powder and liquid drops. Three scoops of powder and three drops of liquid will provide an adequate amount of material to seat one typical crown.

Shake the jar to fluff the RelyX™ Luting powder before dispensing. Insert the scoop into the jar, overfill it with loosely packed powder and withdraw it against the plastic leveler to remove the excess powder and obtain a level scoop. Dispense the desired number of powder scoops onto the mixing pad.

Note: The glass ionomer powders are sensitive to high humidity. Store with jar caps securely tightened and away from high humidity.

To obtain a proper liquid drop size, hold the RelyX Luting cement liquid vial vertically with the dropper tip down and without the tip contacting the mixing pad. Squeeze the vial to dispense the desired number of liquid drops onto the mixing pad.

5. Mixing: Using a cement spatula, mix the powder into the liquid. To minimize water evaporation and maximize working time, continue spatulation of the powder and liquid to a small area of the mixing pad. All of the powder should be incorporated into the liquid within 30 seconds.
6. Working Time of the standard powder/liquid ratio is at least 2.5 minutes from the start of mix at a room temperature of 73°F (23°C). Higher temperatures and vigorous spatulation will shorten working time. Lower temperatures will lengthen working time.

Note: Working time can be lengthened by using refrigerated liquid or by mixing on a cold slab.
7. Crown Placement: Load the crown by spreading a layer of the cement over all the interior surfaces of the crown. Seat crown. Maintain pressure on crown to maintain position during setting process
8. Clean up excess: Excess material can be removed when cement reaches a waxy stage after a minimum of 3 minutes from placement in the mouth (37°C or 98°F). Use a suitable instrument for this purpose.

Storage and Use

1. Shelf life at room temperature is 24 months. See outer package for expiry date.
2. The glass ionomer system is designed to be used at room temperatures of approximately 70-75°F (21-24°C). Replace caps immediately after use.
3. Glass ionomer powders are sensitive to high humidity. Store with jar caps securely tightened and away from high humidity.
4. Do not substitute Vitremer™ Core Buildup/Restorative powder or liquid manufactured by 3M ESPE, for RelyX Luting cement powder or liquid.
5. No person is authorized to provide any information, which deviates from the information provided in the instruction sheet.

Warranty

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability

Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

RelyX™ Luting Plus Cement

Description of Product

RelyX Luting Plus cement is a self-curing, radiopaque, fluoride-releasing, resin-modified glass ionomer luting cement. The cement consists of a base and catalyst paste packaged in the Clicker™ Dispensing System. The paste/paste formulation offers greater convenience over the traditional powder/liquid cement systems. The cement is available in a white shade.

Indications For Use

- Cementation of porcelain-fused-to-metal (PFM) crowns and bridges
- Cementation of metal crowns, bridges, inlays and onlays (including prefabricated provisional metal crowns)
- Cementation of all-alumina or all-zirconia strengthened restorations (i.e. Lava™ All-Ceramic System or Procera® AllCeram restorations)
- Cementation of prefabricated or cast posts
- Cementation of orthodontic appliances

Precautions

RelyX Luting Plus cement contains acrylate resins including HEMA (2-hydroxyethylmethacrylate). Avoid use of this product on patients with known acrylate allergies. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured resins. Use of protective gloves and a no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly used gloves. If cement contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If accidental contact with eyes or prolonged contact with oral soft tissue occurs, flush with large amounts of water. If irritation persists, consult a physician.

Pulp Protection

Cover areas in close proximity to the pulp by applying small amounts of hard-setting calcium hydroxide material (e.g., Alkaliner™ MiniTip™ Calcium Hydroxide Liner, manufactured by 3M ESPE) or resin-modified glass ionomer liner (e.g., Vitrebond™ Light Cure Glass Ionomer Liner/Base, manufactured by 3M ESPE) prior to taking an impression for the final restoration.

Preparation

1. Remove the temporary restoration and thoroughly clean the preparation of any temporary cement residue using an oil-free pumice paste.
2. Rinse the prepared tooth or cavity with a water spray, and dry with air, cotton, or a paper tip. Leave tooth surface moist. Do not overdry.
3. Try in final restoration and check for fit. Adjust if necessary.
4. Thoroughly clean the bonding surface of the restoration.
5. Keep area isolated from blood and saliva contamination during cementation process.

Dispensing and Application

1. For first time use, remove the Clicker™ Dispenser from the foil package. Discard foil.
2. Remove cap from the Clicker dispenser by holding down the cap lever and sliding the cap off of the dispenser.

For first time use from a new cartridge, dispense a small amount of material to ensure even dispensing. Discard this material.

3. Fully depress clicker lever to dispense “1 Click” of cement onto mix pad. Allow paste to fully extrude, then release lever. Repeat dispensing process for additional material. The paste is automatically dispensed in equal volumes. (The actual weight ratio dispensed is 1.3:1)

Note: Dispense and mix cement immediately prior to use to avoid water evaporation and drying out of the cement pastes.

4. Wipe the dispenser tips clean with gauze to prevent cross contamination of the two pastes.
5. Replace cap by sliding onto dispenser until securely latched and an audible click is heard.
6. Using a plastic or metal cement spatula, mix the pastes together for 20 seconds until a uniform color is achieved. Avoid the incorporation of air bubbles.

The working time of the mixed cement is 2.5 minutes at 23°C/73°F. Higher temperatures and longer mix times may shorten the working time. Lower temperatures will lengthen the working time.

7. Apply a thin layer of cement to the inside surface of the restoration. The cement may also be applied directly to the tooth surface for inlay/onlay restorations.
8. Seat the restoration with light pressure. Maintain light pressure on the restoration to hold proper positioning during setting process.

Clean Up and Finishing

- Remove excess cement when it has reached a waxy stage after 2 minutes from placement in the mouth. Use a suitable instrument (e.g. scaler, explorer) for this process.
- Finish restoration and check occlusion when material has completely set after 5 minutes from placement in the mouth.

Storage and Use

- Shelf life at room temperature of an unopened foil package is 24 months. Expiry date is noted on package.
- Keep dispenser in foil package until time for initial use. Once the foil pouch is opened, the shelf life of the cement in the Clicker™ Dispenser is 6 months. Refrigeration of material can extend shelf life. Allow material to come to room temperature prior to use.
- RelyX™ Luting Plus Cement is designed to be used at room temperature of 21-24°C or 70-75°F.
- Store Clicker paste dispensers in a cool environment. Do not expose the cement to elevated temperatures. Do not allow the pastes to dry out. Store with cap securely attached to the dispenser.

- The Clicker™ Dispenser can be cleaned and disinfected by following standard infection control practices for surfaces that have been touched.

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Questions and Answers

How many applications can be done out of each system?

For the RelyX™ Luting Cement powder/liquid system it is recommended to use 3 scoops to 3 drops of liquid for a single crown. Based on these ratios, approximately 80 single units can be seated out of one set of powder and liquid.

For the RelyX™ Luting Plus Cement paste/paste system it is recommended to dispense 2 “clicks” of material out of the Clicker™ Dispenser for a single crown. Based on this amount, approximately 40 single units can be seated out of one Clicker dispenser. There are 80 total clicks of material out of a single Clicker dispenser. The back of the plunger has a scale that shows how many clicks are remaining in the Clicker dispenser.

What is the shelf life for the cements?

For the RelyX Luting cement powder/liquid system, the shelf life is 2 years. During use it is very important to make sure that powder vial is completely sealed after use to avoid moisture contamination of the powder, which can eventually cause slow setting.

For the RelyX Luting Plus cement paste/paste system, the shelf life is 2 years. The cement Clicker dispenser is packaged in a foil pouch. This is to help minimize water loss out of the product. Keep the Clicker dispenser in the foil pouch until it is ready for use. Once the foil pouch is opened, the product in the Clicker dispenser then has 6 months of shelf life. Refrigeration can extend this shelf life but make sure to allow the paste to come to room temperature before trying to dispense. It is important to make sure the Clicker dispenser cap is securely latched after use to avoid water loss and drying out of the pastes.

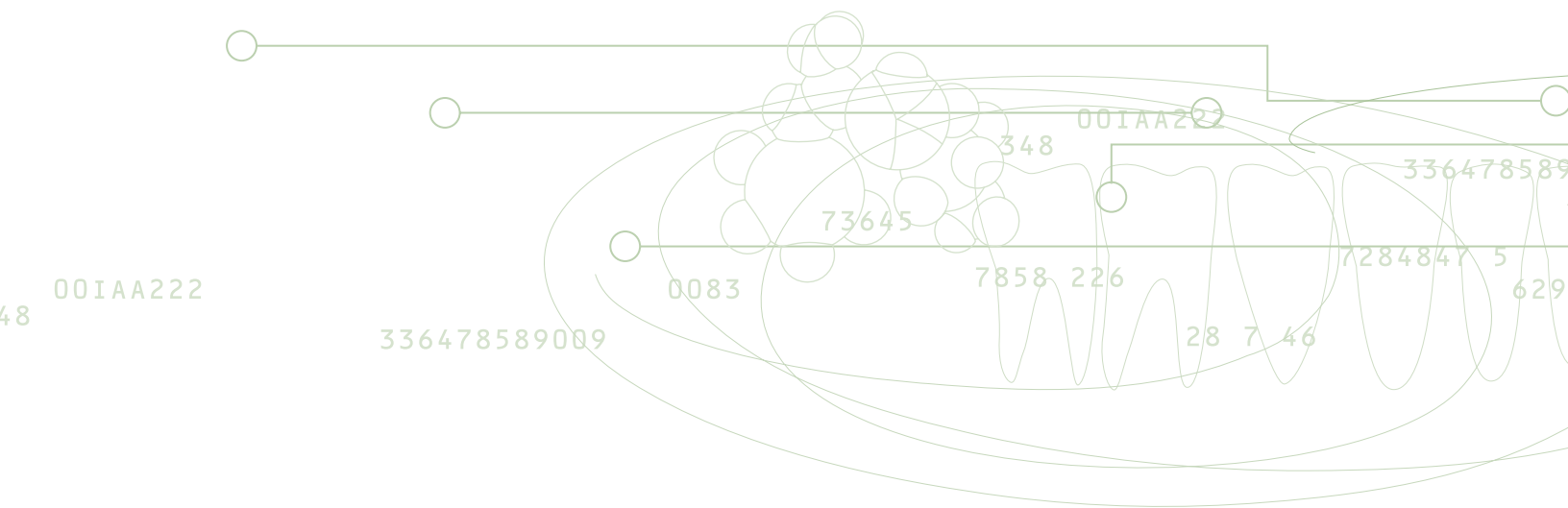
Are the RelyX Luting cement and RelyX Luting Plus cement indicated for use with ceramic restorations?

The only ceramic restorations indicated are the strengthened-core ceramic restorations fabricated out of alumina (i.e. Procera® AllCeram) or zirconia (i.e. Lava™ All-Ceramic System).

Technical Data Summary

| | RelyX™ Luting Plus Cement | RelyX™ Luting Cement | FujiCEM™ | Fuji 1® |
|--|------------------------------|-------------------------|--------------|--------------|
| Compressive Strength (MPa) | 160.0 ± 8.8 | 111.7 ± 26.0 | 121.0 ± 21.4 | 180.7 ± 22.2 |
| Diametral Tensile Strength (MPa) | 25.5 ± 2.3 | 21.9 ± 4.4 | 17.6 ± 4.8 | 21.6 ± 1.6 |
| Flexural Strength (MPa) | 31.6 ± 4.1 | 27.6 ± 4.3 | 24.8 ± 9.5 | 7.8 ± 4.3 |
| Shear adhesion to dentin (MPa) | 5.7 + 1.8 | 5.0 + 4.5 | 1.5 + 2.2 | 3.2 + 1.0 |
| Shear adhesion To enamel (MPa) | 10.3 + 1.8 | 8.4 + 2.4 | 5.7 + 3.4 | 3.3 + 1.6 |
| Shear adhesion to metal (Rexillum III) (MPa) | 10.5 + 2.6 | 7.5 + 1.1 | 9.6 + 3.1 | 6.7 + 1.6 |
| Shear adhesion to alumina (Procera® AllCeram) (MPa) | 14.2 + 1.9 | 11.3 + 2.9 | 8.6 + 1.0 | 2.8 + 1.6 |
| Shear adhesion to zirconia (Lava™ All-Ceramic) (MPa) | 9.2 + 2.5 | 14.4 + 1.5 | 10.6 + 2.6 | 2.8 + 0.5 |
| Shear Adhesion to amalgam core build-up (MPa) | 8.7 + 2.7 | 6.6 + 1.9 | 4.8 + 2.8 | 4.4 + 1.2 |
| Shear adhesion to glass ionomer core build-up (MPa) | 6.7 + 1.9 | 8.4 + 1.6 | 5.8 + 1.2 | 5.4 + 1.9 |
| Shear adhesion to composite resin core build-up (MPa) | 5.3 + 2.1 | 14.6 + 4.1 | 11.4 + 2.3 | 5.1 + 0.3 |
| Film thickness (microns) | 15.3 ± 1.5 | 17.0 ± 2.6 | 11.3 ± 3.2 | 21.3 ± 2.5 |
| Radiopacity (mm) | 1.42 ± 0.01 | 1.53 ± 0.02 | 1.32 ± 0.08 | 1.90 ± 0.1 |

Source: 3M ESPE Lab Test Data



3M ESPE

Dental Products

3M Center
Building 275-2SE-03
St. Paul, MN 55144-1000
USA

3M Canada

Post Office Box 5757
London, Ontario N6A 4T1
Canada
1-800-265-1840 ext. 6229



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waste paper

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